K090512

MAR 27 2009

510(k) Summary
21 CFR 807.92(a)

PowerPort™ *duo* M.R.I.™ Implanted Port
with 9.5 Fr. Dual Lumen (D/L) ChronoFlex® Polyurethane Catheter
February 20, 2009

General Provisions	Submitter of 510(k): Bard Access Systems, Inc. (BAS) PreMarket Notification: [Wholly owned subsidiary of C.R. Bard, Inc.] Salt Lake City, UT 84116 Contact Person: Angela M. Brady, Regulatory Affairs Specialist Device Trade Name: PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex® Polyurethane Catheter
Predicate Devices	**Predicate Device Name** / **510(K)** / **Concurrence Date** PowerPort™ M.R.I.™ Implanted Port with 8.0 Fr. ChronoFlex® Polyurethane Catheter / K063377 / January 25, 2007 Trade Name: PowerPort™ M.R.I.™ Implanted Port with 8.0 Fr. ChronoFlex® Polyurethane Catheter Common/Usual Name: Implanted Infusion Port & Catheter Classification Name: LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter CFR Reference: 21 CFR §880.5965, Class II Classification Panel: General Hospital **Predicate Device Name** / **510(K)** / **Concurrence Date** X-Port™ *duo* Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter / K034065 / January 15, 2004 Trade Name: X-Port™ *duo* Implanted Port with 9.5 Fr. Dual Lumen (D/L) ChronoFlex® Polyurethane Catheter Common/Usual Name: Implanted Infusion Port & Catheter Classification Name: LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter CFR Reference: 21 CFR §880.5965, Class II Classification Panel: General Hospital
Classification	21 CFR §880.5965, Class II LJT – Subcutaneous, Implanted, Intravascular Infusion Port
Performance Standards	Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.
Intended Use	PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter devices are implanted vascular access devices designed to provide long-term, repeated access to the vascular system.
Indications for Use	PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.
Technological Characteristics	Technological similarities between the subject PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter and the cited predicate devices remain identical. There are no additional questions raised regarding safety or effectiveness of the subject PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation, and indications for use to current commercially available implanted port cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C.R. Bard, Incorporated
C/o Ms. Angela M. Brady
Regulatory Affairs Specialist
Bard Access Systems
605 North 5600 West
Salt Lake City, Utah 84116

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Re: K090512
Trade/Device Name: PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex® Polyurethane Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: February 24, 2009
Received: February 26, 2009

Dear Ms. Brady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: PowerPort™ *duo* M.R.I.™ Implanted Port with 9.5 Fr. D/L ChronoFlex® Polyurethane Catheter

Indications for Use:

The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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